SUMMARY OF REVISIONS:

POLICIES AND
STANDARD OPERATING PROCEDURES
FOR THE
DURHAM VETERANS AFFAIRS MEDICAL CENTER
HUMAN RESEARCH PROTECTION PROGRAM

VAMC DURHAM

A PUBLICATION OF THE RESEARCH AND DEVELOPMENT SERVICE
DURHAM VAMC
508 Fulton Street
Durham, North Carolina 27705

July 2005
Revisions from: October 2006, April 2008, September 2008, September 2009, October 2010, March 2011, May 2011, November 2011, January 2013, March 2013, August 2013, and June 2014, March 2015, August 2015, December 2015, April 2016

CURRENT: August 2016

REVISIONS

Major revisions from the December 2015 to April 2016 version included:

SOP #	Title	Change Rationale
GA 102	1.2.2 Competency Checklists	**Added: 1.2.2 Competency Checklists** Vital Sign Competency Initial and Annual Review: • If an employee collects vital signs from patients as part of his/her research duties and as indicated on the Research Scope of Practice, he/she must complete the Durham VAMC Research Vital Sign Competency Initial and Annual Review Checklist. This checklist list must be completed initially and annually so long as his/her research duties include the collection patient vital signs. The competency must be signed and dated by the research staff member and preceptor and submitted to the Research Office. While individuals are accountable for maintaining this competency checklist, it will be retained by the Research Office. For individuals meeting waiver status, the competency checklist should only be completed and submitted initially (ONE-TIME) to indicate waiver status has been met. The checklist must be completed and submitted to the research office whenever there is a change in waiver status. Blood Collection Competency Checklist: • If an employee preforms venipuncture (blood draws) as part of his/her research duties and as indicated on the Research Scope of Practice, he/she must complete the Blood Collection Competency Checklist. This checklist list must be completed initially and annually so long as his/her research duties include blood draws for research purposes. The competency must be signed and dated by the research staff member and preceptor and submitted to the Research Office. While individuals are accountable for maintaining this competency checklist, it will be retained by the Research

SOP #	Title	Change Rationale
		• Office. For individuals meeting waiver status, the competency checklist should only be completed and submitted initially (ONE-TIME) to indicate waiver status has been met. The checklist must be completed and submitted to the research office whenever there is a change in waiver status. If applicable, the current date of Blood Collection Competency must be listed on the Sub-committee for Research Safety (SRS) form Research Using Human Blood, Tissue, or Cell Lines at initial and continuing review.
OR 203	***1.1 Submission Requirements for Initial Review***	Added: • Research Vital Sign Competency Checklist for staff collecting vital signs for research (if not already on file in the Research office and if applicable to the proposed project) • Blood Collection Competency Checklist for staff preforming blood draws for research (if not already on file in the Research office and if applicable to the proposed project) • Data Management and Access Plan (DMAP) that describes the conditions and mechanisms the publications and final data sets resulting from research will be shared with the public.
FO 305	Documentation and Document Management	These records will be retained and destroyed per current VHA Records Control Schedule for research records. ~~until disposition instructions are published in VHA's Records Control Schedule.~~ ***1.2 Document Retention*** After the record retention period has ended, the records will be destroyed per current VHA Records Control Schedule for research records
FO 305	1.2.1 Study Related Documents	Added: a. Data Management and Access Plan (DMAP)
RR 402	***1.1 Minimal Criteria for Approval of Research***	. In some cases the IRB may suggest ~~require~~ that a Certificate of Confidentiality be obtained to protect the research data.

SOP #	Title	Change Rationale
RR 402	***1.1 Minimal Criteria for Approval of Research***	Master list no longer required: ~~N. Master List of all Subjects: Investigators must make a provision to maintain a master list of all subjects from whom informed consent has been obtained whether or not IRB granted a waiver of documentation of informed consent (see 38 CFR16.117(c)). The IRB may waive the requirement for the Investigator to maintain a master list for a given study if both of the following conditions are met:~~ ~~(a) There is a waiver of documentation of informed consent, and~~ ~~(b) The IRB determines that including the subjects on such a master list poses a potential risk to the subjects from a breach of confidentiality.~~ ~~If IRB waives the requirement to maintain such a master list, IRB must provide written documentation in the IRB minutes or IRB protocol file justifying the waiver.~~
CC 601	Investigator Security and Privacy Violations	i. Investigators will immediately (within one hour) report (call or email: VHADURResearchEventReport@va.gov) any theft, loss or compromise of any VA sensitive information. The event reporting group, VHADURResearchEventReport@va.gov, contains includes the ISO and PO. Report lost or stolen computer equipment to the ISO and VA Police (if local). **The VA police do not need to be contacted if the lost or stolen devices contain no VA Sensitive Information (VASI) or PHI.** If not at the VA, call security at your location (hotel, airport, etc.) and call the local police. Obtain phone #, badge #, case #, and copy of report. In addition, the ACOS/R&D, the ISO, the Privacy Officer and IRB must be notified. ii. Any theft, loss or compromise of VA sensitive information must be reported to the IRB within 5 business days of becoming aware of any information security or privacy incident using the Report Form for Privacy and/or Information Security Incidents in VA Research. If further reporting is determined to be necessary the ISO will notify the Medical Center Director who will notify VA Central Office. If the incident is believed to involve criminal activity, the ISO and/or PO will contact the local VA Police and the OIG.

SOP #	Title	Change Rationale
		Research staff will immediately notify the Investigator of any theft, loss, or compromise of VA sensitive information as soon as it is discovered. The Investigator will then follow the above escalation. **Lost or stolen devices related to research that contain no VASI or PHI do not need to be reported to the IRB immediately (within 5 days of learning of the event), but will be reported at continuing review on the adverse event log.**
RI 801	***1.6 Research Records***	Research records will be maintained and destroyed according to the VHA RCS 10-1. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Records will not be destroyed without pre-notification to the facility records manager. ~~The investigators research records are not yet scheduled in VHA RCS10-1 and therefore must be retained until disposition instructions, as approved by NARA, are published in VHA RCS 10-01.~~

Revisions due to the revised VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, dated November 12, 2014:

SOP #	Title	Change Rationale
GA 102	Research Required Training, Education, and Other Research Personnel Documentation	*Section 1.1, Training:* Provided more detail about the type of required training and training interval : Each individual involved in the conduct of human subjects' research (including the MCD, COS, R&D Committee members, and Research Pharmacist) is required to complete <u>training in ethical principles concerning human subjects research</u> ~~an educational module~~. IRB members, Investigators, the research team, and research staff are required to update their research-related educational training every <u>three</u> ~~two~~ years. The training must be completed within the ~~second~~ <u>third</u> full calendar year after the previous training. *Section 1.2, Scope of Practice:* Removed the requirement that Research Scopes of Practice are required annually:

SOP #	Title	Change Rationale
		The scope of practice is required for all research personnel and must be ~~submitted annually and~~ signed by the individual, the individual's supervisor, each Principal Investigator (PI) that the individual works with, and the ACOS/R&D. *Section 1.2.1, Scope of Practice Updates / Revisions:* Removed language that referenced annual submissions: • ~~It is not necessary to immediately remove an obsolete PI from a current Research SOP; instead the individual would remove that PI at the next annual SOP submission.~~
OR 201	Composition of the IRB	*Section 1.1, Membership selection Criteria:* Revised term length for IRB Chairs: The chairperson shall be an employee of the Durham VAMC, appointed by the Medical Center Director for a term of three years ~~one year~~ and may be re-appointed indefinitely.
OR 202	Management of the IRB	*Section 1.5, Compensation:* Revised to reflect current practice: IRB Chairperson(s) may receive protected time to conduct IRB business ~~and may receive compensation from Durham VAMC's research non-profit organization, the Institute for Medical Research (IMR)~~.
OR 203	Duties of IRB Members	*Section 1.2, Term of Duty:* Revised term length for IRB Chairs: The Durham VAMC IRB Chairperson(s) must be appointed by the Medical Center Director for a term of 3 years ~~one year~~ and may be re-appointed indefinitely.
FO 305	Documentation and Document Management	*Section 1.5, Policy*: Added clarification statement: IRB records are the property and responsibility of the local research office. *Section 1.3, IRB Administrative Documents:* Added language per VHA HB 1200.05: • Curriculum Vitae or Resume for each voting IRB member. Note: the resume or CV must be updated at the time of

SOP #	Title	Change Rationale
		appointment or reappointment.
RR 402	Initial Review: Criteria for IRB Approval	*Section 1.1C, Recruitment and Advertisements:* Revised language regarding the posting of documents, flyers, and advertisements for non-VA research: All recruitment and advertisement materials will be reviewed and approved by the IRB to ensure that enrollment and recruitment practices are fair and equitable. ~~The Medical Center Director is responsible for ensuring that recruiting documents, flyers, and advertisements for non-VA research are not posted on or within the premises of the Durham VAMC. Posting of such documents may give the Veteran or visitors to the VA facility the impression that the non-VA study is VA-approved research, the VA supports or endorses the research, or that VA will pay for the research expenses that are incurred.~~ Postings of all advertisements must be limited to the bulletin boards within the Medical Center.
RR 402	Initial Review: Criteria for IRB Approval	Advertisements for non-VA Research Advertisements, flyers, and recruitment documents for non-VA research that supports the VHA's mission and enhances the quality of health care delivery to Veterans may be posted or distributed on VA property as long as the advertisements, flyers, and/or recruitment documents are reviewed qualified Research Office personnel and meet criteria below. The submission must include the advertisement/flyer/recruitment document, current approved protocol, current approved informed consent form, and documentation of current IRB of record approval. Qualified Research Personnel will review outside requests for the posting of recruiting documents, flyers, and advertisements to ensure that the research is relevant to Veterans, the mission of VA, and will not impede current VA research activities. Non-VA research advertisements will not be reviewed by the IRB or Research Committee as if they are VA research, however, members of these committees may be asked for input as appropriate. The following clear and legible disclaimer will be included on all non-VA research recruitment materials: This is not VA research, will not be conducted by VA, has not been reviewed by VA's Institutional Review Board, and is not endorsed by VA. VA is not responsible for any costs incurred by a Veteran if the Veteran enters the study as a research subject. This announcement is being provided for information only. Once these requirements are met, the non-VA research advertisements/flyers/recruitment documents may be posted and/or used in accordance with local policy.

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RR 402	Initial Review: Criteria for IRB Approval	*Section 1.2, Participation of Non-Veterans in Research*: Revised language per VHA HB 1200.05: Other Research. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they s hould be included in VA studies whenever appropriate.~~entered into an approved VA research study when the Investigator can present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.~~ Active duty military personnel may be entered into VA research conducted jointly by VA and DoD or within DoD facilities. All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the Investigator. Investigators must provide notice of privacy practices and acknowledgement for any non-Veteran enrolled in the approved protocol. *Section 3, Responsibility:* Added language: The Medical Center Director is responsible for ensuring that a procedure is in place to review and approve recruiting documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff.
RR 403	Continuing Review: Ongoing	*Section 1.11, Suspensions and Terminations of IRB Approval:* Removed language that was no longer consistent with VHA HB 1200.05: ~~There shall be no grace period beyond the approval period granted by the IRB which shall not exceed one year (365 days). If continuing review does not occur within the timeframe set by the IRB, the research no longer has IRB approval and has to~~

SOP #	Title	Change Rationale
		~~automatically stop. Enrollment for new subjects cannot occur. Continuation of research interventions or interactions in already enrolled subjects should only occur when the IRB or IRB Chair, in consultation with the Chief of Staff (COS) finds that it is in the best interest of individual subjects to do so.~~
RR 404	Continuing Review: Criteria for Renewal	*Section 1,Policy:* Removed language about continuation of research interventions: ~~Continuation of research interventions or interactions in already enrolled subjects should only occur when the IRB or IRB Chair, in consultation with the Chief of Staff (COS) finds that it is in the best interest of individual subjects to do so.~~ *Section 1.6, Expiration of IRB Approval:* Revised language describing what happens when IRB approval expires: If the continuing review does not occur within the timeframe set by the IRB, the IRB approval for the research automatically expires. <u>If approval expires, the investigator must:</u> 1) <u>Stop all research activities including, but not limited to, enrollment of new subjects, analyses of individually identifiable data, and research interventions or interactions with currently participant subjects, except where stopping such interventions or interactions could be harmful to those subjects, and</u> 2) <u>Immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping specified study interventions or interactions. The IRB Chair must determine within 2 business days whether or not such interventions or interactions may continue.</u> ~~Extensions beyond the expiration date will not be granted. If Continuing Review Report forms and other requested progress reports or responses to contingencies are not received as scheduled, the Investigator must cease all research activities on the study and study enrollment until reports are reviewed and approved. This includes stopping recruitment, advertisements, procedures on current participants, and collection of identifiable private information.~~ ~~Should approval lapse, the Research Office will send a letter of notification to the PI. The letter will state that all research activities must stop and that continuation of research~~
RR 404	Continuing Review: Criteria for Renewal	

SOP #	Title	Change Rationale
		~~interventions or interactions in already enrolled subjects should only occur when the IRB or IRB Chair, in consultation with the Chief of Staff (COS) finds that it is in the best interest of individual subjects to do so, as outlined below.~~ ~~The Investigator is responsible for providing a list of participants to the IRB Chair for whom stopping research activities could cause harm.~~
SC 501 SC 501	Vulnerable Populations Vulnerable Populations	*Section 1.3.1, Fetuses:* Added language regarding stem cells: Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding. *Section 1.3.2, Neonates:* Revised language: VA investigators cannot conduct interventions in research that enroll neonates while on official duty, or at VA facilities, or at VA-approved off-site facilities. Note: Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted. ~~Research related to neonates including, but not limited to, observational or interventional research, must not be conducted by VA Investigators while on official duty, or at VA facilities, or at VA approved off-site facilities.~~ *Section 1.3.3, In Vitro Fertilization*: Revised language. Research that involves provision of ~~related to~~ in vitro fertilization services cannot ~~is not to~~ be conducted by VA Investigators while on official duty, or at VA facilities, or at VA-approved off-site facilities. Note: Prospective and retrospective studies that enroll or include pregnant subjects who conceived through in vitro fertilization or other artificial reproductive technologies are permitted. *Section 1.5, Children*: Revised language: 1.5.1 ~~Waiver~~ Requirements: The VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivered to Veterans. Therefore, research involving children must be reviewed carefully by the IRB for its relevance to VA and must not be greater than minimal

SOP #	Title	Change Rationale
SC 501	Vulnerable Populations	risk. The VA medical facility Director must approve participation in the proposed research that includes children. Note: Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. If the biological specimens or data were previously collected, they must have been collected under applicable policies and ethical guidelines. ~~not be conducted by VA Investigators while on official duty or at VA or approved off-site facilities unless a waiver has been granted by the CRADO.~~ If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to children as research subjects (see 45 CFR Part 46, Subpart D, Additional Protections for Children Involved as Subjects in Research). 1.5.2 Criteria for Waiver: ~~Prior to requesting a waiver, the following criteria must be met:~~ ~~(1) The study represents no greater than minimal risk as determined by the IRB.~~ ~~(2) The study meets all requirements in 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research, Sections 46.401 through 46.404, and 46.408.~~ ~~(3) The IRB reviewing the study has appropriate membership to represent children's interests and pediatric expertise.~~ ~~(4) The IRB reviewing the study has specific SOPs regarding children in research.~~ ~~(5) The VA facility Director certifies that the facility is able to respond to pediatric emergencies if the study includes interactions with children at the VA facility.~~ ~~(6) If the sponsor of the research is not VA, the facility Director makes certain that the sponsor of the research has procured appropriate liability insurance.~~ 1.5.2~~3 Waiver~~ Application To conduct research involving children~~request a waiver~~, the following information must be submitted to the IRB~~ORD~~ for each protocol: (1) A cover letter signed by the Investigator~~VA facility Director~~ that contains the following information: (a) Evidence ~~Certification by the VA facility Director~~ that the facility is able to respond to pediatric emergencies if the study includes an interaction with children at the VA facility. (b) Any additional safeguards that have been incorporated into the clinical site where children will be studied.

SOP #	Title	Change Rationale
SC 501	Vulnerable Populations	(c) Information on the study's funding source and on liability coverage if the sponsor is not VA. ~~(d) Certification that the IRB has determined the study to be of no greater than minimal risk and has approved the study.~~ ~~(e) A statement that the required elements of 45 CFR 46 Subpart D have been met.~~ (~~f~~d) A description of the relevance to Veterans' health of both the study and the inclusion of children in the study. (e) If the sponsor of the research is not VA, the sponsor has procured appropriate liability insurance. ~~(2) A copy of the study protocol, the informed consent form, the assent document, and HIPAA authorization. The informed consent document signed by the parent or guardian is the vehicle for parent or guardian permission. Provisions for permission by parents or guardians must be documented in accordance with and to the extent required by 38 CFR 16.117.~~ ~~(3) Minutes of the IRB meeting approving the study. The IRB minutes need to reflect the discussion regarding level of risk, the informed consent and assent forms, the Investigators' qualifications to conduct research involving children, and any additional safeguards incorporated into the protocol.~~ (~~4~~2) If the study involves biological specimens or data collected from children, in addition to the preceding requirements, the following must be submitted: (a) A discussion of how the biological specimens or data were, or will be, obtained and under what consents or authorization. (b) If the biological specimens or data were, or will be, collected for research purposes, the IRB approval, the informed consent form, and the HIPAA authorization for the research. (c) If biological specimens or data were, or will be, collected from an international site, approval by the medical facility Director~~waiver from the CRADO~~ for international research. (d) Plans for future use of biological specimens or data. The medical center Director will review the minutes of the IRB meeting approving the study. The IRB minutes need to reflect the discussion regarding level of risk, the informed consent and assent forms, the Investigators' qualifications to conduct research involving children, and any additional safeguards

SOP #	Title	Change Rationale
SC 501	Vulnerable Populations	incorporated into the protocol. *Section 1.6, Pregnant Women:* Revised language: This section applies to women who are pregnant at the time they are entered into a study. It does not preclude entering women of child bearing potential into research studies ~~including studies whose interventions include FDA's Categories for Drug Use in Pregnancy's Category C drugs~~. Research involving pregnant women may be conducted at the Durham VAMC if the research is relevant to the health of Veterans. Women who are known to be pregnant and/or their fetuses may be involved in research if all of the requirements of 45 CFR 46.204 are met including informed consent requirements and the following ethical and scientific criteria: a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or fetus. If there is no such prospect of benefit, t hen the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means; c) Any risk is the least possible for achieving the objectives of the research; and d) The medical facility Director certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research. Specifically, the Director must certify that the facility is able to respond to obstetric emergencies if the research involves an intervention greater than minimal risk in pregnant women at the facility. ~~This section applies to women who are pregnant at the time they are entered into a study. It does not preclude entering women of child bearing potential into studies including studies whose interventions include FDA's Categories for Drug Use in Pregnancy's Category C drugs. Women of child bearing potential may not be entered into studies involving the use of FDA Categories for Drug Use in Pregnancy's Category D or X~~

SOP #	Title	Change Rationale
SC 501	Vulnerable Populations	~~drugs unless a waiver is obtained from the CRADO. Pregnant women may be the focus of the research if all of the following conditions are met (45 CFR 46.204):~~ ~~a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;~~ ~~b) One of the following was true:~~ ~~1) The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;~~ ~~2) Or the risk to the fetus was not greater than minimal and the purpose of the research was the development of important biomedical knowledge which could not be obtained by any other means.~~ ~~c) Any risk is the least possible for achieving the objectives of the research;~~ ~~d) Adequate provision has been made to monitor the risks to the subject and the fetus;~~ ~~e) The woman's consent or the consent of her LAR is obtained in accord with the informed consent provisions of DHHS subpart A- Basic HHS Policy for Protection of Human Research Subjects, unless altered or waived in accord with 46.101(i) or 46.116(c) or (d);~~ ~~f) The woman or her LAR, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;~~ ~~g) For children as defined in 46 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D;~~ ~~h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;~~ ~~i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and~~ ~~j) Individuals engaged in the research will have no part in~~

SOP #	Title	Change Rationale
SC 501	Vulnerable Populations	~~determining the viability of a fetus.~~ ~~An activity permitted may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:~~ • ~~The purpose of the activity is to meet the health needs of the mother;~~ • ~~His identity or whereabouts cannot reasonably be ascertained;~~ • ~~He is not reasonably available; or~~ • ~~The pregnancy resulted from rape.~~ *Section 1.7, Subjects Who Lack Decision-making Capacity:* Revised language: 1.7.1 Determination of ~~Criteria for Decision-Making~~ Capacity When planning to enter subjects with impaired decision-making capacity, investigators must address in the protocol how they will determine when surrogate consent (i.e., a LAR) will be required. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity. However, the IRB must review and approve the plan to ensure that it is appropriate given the population and setting of the research. Note: Individuals ruled incompetent by a court of law are considered to lack decision-making capacity. 1.7.3 Criteria for Enrollment: Individuals who lack decision-making capacity may be enrolled in protocols if: (1) The IRB determines that the proposed research entails: (a) No greater than minimal risk to the subject ~~as determined by the IRB~~; or (b) Presents a greater probability of direct benefit to the subject than harm to the subject; or ~~If the research presents some probability of harm, there must be at least a greater probability of direct benefit to the subject; or~~ (c) Greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

SOP #	Title	Change Rationale
		(2) The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder (e.g., Alzheimer's) leading to the individual's lack of decision-making capacity ~~is being studied~~, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke)~~, but only if the study cannot be performed with only persons who have decision-making capability~~.
SC 502	Categories of Research	*Section 1.9, Collaborative Research:* Added new section. *Section 1.10, Certificates of Confidentiality:* Added new section.
SC 505 SC 505	International Research International Research	Revised language to be in compliance with VHA HB 1200.05: *Section 1, Policy:* This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. ***NOTE:*** *Research conducted at US military bases, ships, or embassies is not considered international research.* S~~This includes s~~ending ~~such~~ specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA Investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the US or Puerto Rico and accessed via a secure connection is not considered international research. ~~It also includes a VA's serving as a coordinating center for an international research project.~~ *Section 1.1, Multi-Site Trials* International research includes multi-site trials involving non-US sites where ~~Multi-site trials are covered under this definition if any of the following apply~~: (1) VA is the study ~~a~~ sponsor; (2) a VA investigator is the overall study-wide PI~~VA functions as the coordinating center~~; (3) VA holds the Investigational New Drug (IND)~~subcontracts to~~

SOP #	Title	Change Rationale
SC 505	International Research	~~a foreign site~~; or (4) the VA manages the data collection and the data analyses~~The PI for the total study is a VA Investigator; or~~ ~~(5) The VA Investigator is specifically collaborating with an international Investigator and the VA Investigator sends data or human biological specimens outside the U.S., or receives them from outside the U.S.~~ ***NOTE**: I*nternational research does not include studies in which ~~This requirement does not apply if~~ *VA is only one of* multiple ~~the~~ *participating sites* where the overall study-wide PI is not a VA investigator~~and the trial does not meet the preceding conditions.~~ *Section 1.2, I*RB and Facility Director ~~*CRADO*~~ *Permission* Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the US who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the US. All international research must be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO~~Permission must be obtained from the CRADO, or designee, prior to initiating any VA-approved international research~~. The Investigator should work with the Research Office to ensure medical facility Director approval.~~This applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including agreements, MOU, Cooperative Research and Development Agreements (CRADA), grants, or contracts. The CRADO, or designee, will not grant permission for an international research study involving prisoners as research subjects.~~ *Section 3, Responsibility:* Facility Director's responsibilities: In addition to VA facility Director responsibilities delineated elsewhere in this document, the facility Director is responsible for approving the request for permission to conduct international research~~ prior to forwarding it to the CRADO for action and ensuring permission has been obtained from the CRADO, or designee, for the international

SOP #	Title	Change Rationale
		~~research~~ prior to its initiation by an Investigator at the facility. PI responsibilities: In addition to the PI responsibilities delineated elsewhere in this document, the PI is responsible for obtaining approval from the facility Director~~, obtaining permission from the CRADO, or designee,~~ in writing before initiating an international research study, and conducting research in compliance with this document and all other applicable VA and other Federal requirements including those for protecting human subjects, tissue banking, use of databases, federal criminal laws, and the Standards of Ethical Conduct for Employees of the Executive Branch.
IC 701	General Requirements and Documentation of Informed Consent	*Section 1.1, General Requirements for Informed Consent:* Removed requirement to use VA Form 10-1086; instead, Investigators must use the currently-approved ICF template (NOTE: This change was made numerous times throughout this SOP, but each change is not documented here): d. Informed Consent Form. The ~~most~~ current IRB-approved template ~~version of VA Form 10-1086, Research Consent Form~~ must be used as the basis for the informed consent form. *Section 1.2, Required Elements of Informed Consent:* Revised language to be consistent with VHA HB 1200.05: b. Other Elements of Informed Consent Required by VA. In addition to the elements for informed consent required by the 38 CFR Part 16, VA requires the following elements of informed consent:
IC 701	General Requirements and Documentation of Informed Consent	(1) Any payments the subject is to receive for participating in the study (2) Any real or apparent conflict of interest by investigators where the research will be performed; (3) A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations. Additionally, t~~ (1) T~~he name of the study~~.~~ ~~t~~ ~~(2) The name of the PI: T~~he name of the PI~~, (~~ ~~and,~~ in multi-site

SOP #	Title	Change Rationale
IC 701	General Requirements and Documentation of Informed Consent	studies, the name of the LSI), and t~~.~~ ~~(3) T~~he sponsor of the study should also be included. *Section 1.3.1, Common Rule Requirements:* Revised language to be in compliance with VHA HB 1200.05: G. When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. *Note: Some Veterans are required to pay copayments for medical care and services specifically related to their medical care provided by VA. These co-payment requirements will continue to apply to medical care and services that are not part of the research procedures or interventions.* *Section 1.4, Consent for Photographs, Voice, or Video Recordings for Research Purposes:* Revised language to be in compliance with VHA HB 1200.05: The research informed consent process must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how those items will be used for research, and whether those items will be disclosed outside VA. An informed consent process to take a photograph, video, and/or audio recording cannot be waived by the IRB. Note that in certain instances (e.g., phone or internet survey when data does not leave VA) the IRB may grant a waiver of documentation of informed consent (the participant does not sign a consent form) and a HIPAA waiver. The consent for research does not give legal authority to disclose the photographs, videos, and/or audio recordings outside VA. A HIPAA authorization is needed to make such disclosures. If the photograph, video, and/or audio recording will be shared with non-VHA entities, then the Investigator must obtain a signed HIPAA authorization. If the photograph, video, and/or audio recording will not be

SOP #	Title	Change Rationale
IC 701	General Requirements and Documentation of Informed Consent	shared outside of VA and if the materials are not collected on VA property, then it is sufficient for the PI to conduct an informed consent process that includes information about the recording in the consent (i.e., in-person with an informed consent form), or consent script (i.e., an informed consent process with an ICF waiver of documentation), to have a HIPAA waiver in place, to document verbal consent (if applicable), and record in each separate session the Veteran's verbal consent to be recorded. ~~a.~~ Informed Consent for Research~~: Informed consent for research must be obtained from each research subject before taking photographs or making voice or video recordings that will be used for research purposes. Unless IRB grants a waiver of documentation of informed consent for research, the informed consent form for research (i.e., VA Form 10-1086) must include a discussion of why photographs, or voice or video recordings are being taken for the research, who will have access to them, and what their disposition will be after the research is completed.~~ ~~b.~~ VA Form 10-3203, Consent for Use of Picture and/or Voice.~~ VA Form 10-3203 documents permission for pictures, video, and voice recordings to be made or taken. In the conduct of research, VA Form 10-3203 must be used in accordance with applicable VA and VHA policy.~~ ~~(1) When the research subject is a patient (either an inpatient or outpatient), the subject must sign VA Form 10-3203 to permit photographs or video and voice recordings that will be used for research purposes even if the IRB has waived the requirement for documentation of informed consent for research (VA Form 10-1086). Photography or recordings cannot occur prior to the patient's granting such permission (VHA Handbook 1907.01).~~ ~~(2) When the research subject is a patient, the subject's signed and dated VA Form 10-3203 must be placed into the medical record along with, if applicable, the signed and dated research informed consent form. The signed VA Form 10-3203 must be obtained and placed in the subject's medical record, even if the IRB has waived documentation of informed consent for research.~~

SOP #	Title	Change Rationale
		Section 1.5, Documentation of Informed Consent: Revised language to be in compliance with VHA HB 1200.05: This form may be read to the subject of the subject's legally authorized representative, but in any event, the investigator shall give either the subject of the representative adequate opportunity to read it before it is signed. e. Copies of Signed Consent Form (3) The Investigator must ensure that the person who administered the consent process enters a Research Consent Note in CPRS. ~~and that the original signed consent form is scanned into CPRS as an attachment to the Research Consent Note.~~
IC 704	Privacy Rule and Research	*Section 1, Policy:* Revised language to be in compliance with VHA HB 1200.05: A written HIPAA authorization signed by the individual to whom the information or record pertains is required when VA health care facilities need to access, collect, develop, use, or disclose~~utilize~~ individual-identifiable health information for a purpose other than treatment, payment, or health care operations (e.g., research) unless there is legal authority (e.g., waiver, limited data set with data use agreement, etc.) to disclose such information. The Durham IRB must approve the use of PHI for all proposed research, but cannot approve a HIPAA authorization document. The Privacy Officer must review the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol.
IC 704	Privacy Rule and Research	Data disclosed under a properly executed HIPAA authorization must be securely transferred according to VA information security requirements. *Section 1.1, Authorization:* VA Form 10-0493 must be used, and HIPAA authorizations are no longer required to be scanned into the medical record: I nvestigators are provided a stand-alone research-specific authorization document (VA Form 10-0493) that is separate from the informed consent document a~~nd based on the official VHA authorization form. This form contains language that the VHA~~

SOP #	Title	Change Rationale
IC 704	Privacy Rule and Research	~~Office of General Counsel has determined is necessary for compliance with several privacy laws to which the VHA is subject~~. Investigators must use the authorization form provided and make it study-specific. The researcher must provide the participant with a copy of the signed Authorization form~~ and append the original to the consent form to be scanned into the medical record~~. *Section 1.5, Preparatory to Research:* Revised language to be in compliance with VHA HB 1200.05: Data repositories (including VA medical records) may be used by VA Investigators for activities that are preparatory to VA research without the requirement to obtain either a HIPAA authorization from the subject or waiver of HIPAA authorization by an IRB or Privacy Board. This includes use of PHI for the preparation of a research protocol prior to submission to the IRB. "Preparatory to research" activity is the only instance of access for research purposes allowed in VHA without a written HIPAA authorization signed by the individual, a waiver of HIPAA authorization by an IRB or Privacy Board, or approval by the IRB. ~~This access is granted only to VHA researchers. Non-VHA researchers may not access VHA data for reviews preparatory to research. Additionally, the following holds true:~~ <u>(1) VA Investigators must not arbitrarily review PHI based on their employee access to PHI until the Investigator documents the following required information as "Preparatory to Research" in a designated file that is readily accessible for those required to audit such information (e.g., Health Information Manager, Privacy Officer, or other designated individual):</u> ~~a. Representations by the Investigator: The Investigator must make the representations necessary for preparatory access as required by the HIPAA Privacy Rule and document it in the Investigator's research files. The representations required by the HIPAA Privacy Rule are:~~ a) ~~(1)~~ The access to PHI is only to prepare a protocol; b) ~~(2)~~ No PHI will be removed from the covered entity (i.e., VHA); and c) ~~(3)~~ <u>Access to</u> ~~The~~ PHI ~~accessed~~ is necessary for preparation of the research pro<u>tocol</u>~~posed~~. <u>(2) Non-VA researchers may not obtain VA information for</u>

SOP #	Title	Change Rationale
IC 704	Privacy Rule and Research	preparatory to research activities without appropriate VA approvals. (3) During the preparatory to research activities the VA Investigator: a) Must only record aggregate data. The b) ~~b. Aggregate Data: Only aggregate data may be recorded in the researcher's files, and these~~ aggregate data may be used only for background information, to justify the research, or to show that there are adequate numbers of potential subjects to allow the Investigator to meet enrollment targets or sample size requirements. c) Must not ~~d)~~ e) ~~c. No Recording of Individually Identifiable Health Information: Individually identifiable health information may not be~~ record~~ed~~ any individually identifiable health information; and ~~f)~~ Must not use any individually identifiable information to ~~.~~ ~~g)~~ h) ~~d. No Recruiting From Data: Data or information reviewed may not be used for contacting or~~ recruit~~ing~~ subjects. Note: Preparatory activities can include reviewing database output (computer file or printout) containing identifiable health information generated by the database owner, if the investigator returns the database output to the database owner when finished aggregating the information. (4) Contacting potential research subjects and conducting pilot or feasibility studies are not considered activities preparatory to research. (5) Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.~~e. Repository Requirements: Investigators must comply with all other access requirements set by the repository of interest.~~
RI 801 RI 801	Investigator Responsibilities Investigator Responsibilities	Section 1, Policy: Revised language to be in compliance with VHA HB 1200.05: The Investigator is responsible for personally conducting and supervising all study-related activities. The Investigator must give first priority to the protection of research subjects. The

SOP #	Title	Change Rationale
RI 801	Investigator Responsibilities	Investigator must hold a current VA appointment to conduct VA research. Investigators and co-Investigators must be identified on the IRB application and must provide credentials, conflict of interest statements or other documentation required by VA and local facility policies. *Section 1.1, Investigator Responsibilities:* Added language regarding contractors, limited data sets, documentation in the medical record: J. Obtaining Informed Consent: If the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or are involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the PO must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm. The investigator must ensure that all original signed and dated informed consent documents are maintained in the investigator's research files, readily retrievable, and secure. I. Ensuring HIPAA Authorization is Obtained: This means ensuring that no human being is involved as a subject in research unless the Investigator or a designee formally and prospectively designated in writing in the protocol by the Investigator has obtained legally effective HIPAA authorization for the use and disclosure of the subject's PHI, or has obtained Privacy Board or IRB-approved waiver of HIPAA authorization, unless there is a limited data set and appropriate DUA. M. Ensure that the research and consent process is documented in the medical and research record: (1) Ensure that the person who administered the consent process enters the Research Consent Note in CPRS ~~and that the original signed consent form and HIPAA authorization is scanned into CPRS as an attachment to the Research Consent Note~~. N. Ensuring Proper Research Contacts for Participants~~Performing Subject Outreach: This means ensuring that, as part of the local VA facility's Research Subject Outreach Program, the Investigator is responsible for~~: The investigator must ensure

SOP #	Title	Change Rationale
RI 801	Investigator Responsibilities	~~O. (1) Making every reasonable effort to make available the informational brochure, "Volunteering in Research – Here Are Some Things You Need To Know," (http://www.research.va.gov/programs/pride/veterans/tri-fold.pdf) to potential research subjects in settings where Investigators may recruit subjects (e.g., clinic waiting areas), and to prospective subjects, and their surrogates where applicable, when the individuals are approached to take part in a study.~~ O. Ensuring Appropriate Telephone Contact with Subjects: (1) Initial Contact: … Note: If a research repository from a previous study is used to identify subjects, there must be an IRB approved HIPAA waiver for this activity in the new protocol. (2) If a contractor makes the initial contact by letter, the VA investigator must sign the letter. *Section 1.2, Advertisements:* Revised language to be in compliance with VHA HB 1200.05: ~~Advertisements for non-VA research may not be posted on or within the premises of the Durham VAMC.~~ Postings of all advertisements must be limited to the bulletin boards within the Medical Center. *Section 1.5, Student/Trainee-Conducted Research:* Revised language to be in compliance with VHA HB 1200.05: Trainees (e.g., students, residents, or fellows of any procession) may serve as participants, but not PIs within a VA facility. Trainees may use VA human subjects data, or use human biological specimens that have been collected within VA for clinical, administrative, or research purposes only when: *1.* The study has been approve by the local VA medical facility and IRB, if appropriate; and *2.* Either they are enrolled in an institution with an educational affiliation agreement with that VA facility, or directly appointed to a VA training program that has no external institutional sponsorship (e.g., VA Advanced Fellowship.~~Only students and other trainees (including residents and fellows), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as Investigators within a VA facility, or use data, or human biological specimens that have been collected within VA for clinical, administrative, or~~

SOP #	Title	Change Rationale
		~~research purposes.~~ ***NOTE:*** *A waiver may be obtained from the CRADO under special circumstances.* ~~All activities that meet the definition of research with human subjects and that are conducted by a student for a class project or for work toward a degree must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include: (i) All master's theses and doctoral dissertations that involve human subjects; and (ii) All projects that involve human subjects and for which findings may be published or otherwise disseminated. All students/fellows applying for IRB review must obtain the signature of their service chief on the Signature Page of the Request to Review.~~ A VA Investigator sufficiently experienced in the area of the trainee's research interest must serve as PI ~~or co-PI~~ and is responsible for oversight of the research and the trainee/student. The PI ~~or co-PI~~ is responsible for ensuring the trainee/student complies with all applicable local, VA and other federal requirements.
RI 802	Research Protocol	*Section 1, Policy:* Revised language to be in compliance with VHA HB 1200.05: The Investigator is responsible for creating and maintaining a valid research protocol that is relevant to the health or welfare of the Veteran population. *Section 1.1, Investigator Responsibility for Drafting a Research Protocol:* Revised language to be in compliance with VHA HB 1200.05: Investigators must: a. Ensure research is scientifically sound and describes the research objectives, background, and methodology;
RI 803	Research Records and Documentation of Research	*Section 1, Policy:* Revised language to be in compliance with VHA HB 1200.05: A VHA health record must be created or updated, and a progress note created, for all research subjects (Veterans or Non-Veterans) who are admitted to VA facilities as in-patients, treated as outpatients at VA facilities, or when research procedures or interventions are used in or may impact the

SOP #	Title	Change Rationale
RI 803	Research Records and Documentation of Research	medical care of the VA research subject at a VA facility or at facilities contracted by VA to provide services to Veterans (e.g., contract CBOCs or contract nursing homes) (see VHA Handbook 1907.01). Informed consent documents are not required to be in the health record. *Section 1.2, Research Consent Notes:* Removed ICF and HIPAA authorization scanning requirements: ~~In addition, the following documents must be scanned and attached to the Research Consent Note as soon as possible but no later than 14 days after the subject signs consent, as applicable:~~ ~~Signed and dated informed consent form (VA form 10-1086);~~ • ~~HIPAA authorization for data use or disclosure;~~ • ~~Consent for Use of Picture and/or Voice (VA Form 10-3203).~~ *Section 1.3, Research-Study Participant Notes (Clinical Warnings)*: Removed mandatory flagging requirements; now the IRB has the option to request them. ~~VHA Handbook 1200.05 describes when VHA health record must be flagged; however, t~~The IRB will notify the Investigator at time of initial review when the research requires a mandatory Clinical Warning. The IRB may require that t~~T~~he patient health record ~~must~~ be flagged if the subject's participation in the study involves: • Etc. In general, the IRB will not require a Clinical Warning if: • participation only involves one encounter, or • participation only involves the use of a questionnaire, or • participation only involves the use of previously collected data or biological specimens, or • identification of the subject in a study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk due to potential harm resulting from breach of confidentiality. *1.3.3, Waiver of Research-Study Participant Notes (Clinical Warnings):* Deleted; language added to section 1.3. ~~The IRB may waive the requirement to place a flag in CPRS if:~~ • ~~participation only involves one encounter, or~~

SOP #	Title	Change Rationale
		• ~~participation only involves the use of a questionnaire, or~~ • ~~participation only involves the use of previously collected data or biological specimens, or~~ • ~~identification of the subject in a study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk due to potential harm resulting from breach of confidentiality.~~ *Section 1.6, Research Records:* Added new section.
QA 901	Quality Assurance / Continuous Quality Improvement Program	*Section 1.1, Evaluation of the HRPP:* Removed scanning requirement: B. The institution monitors the performance of Investigators in implementing informed consent requirements. The institution evaluates the following via the Research Compliance Officer's (RCO) informed consent audits: 11. ~~Scanning the consent form into CPRS.~~
QA 904 QA 904	Research Participant Outreach Program Research Participant Outreach Program	*Section 1, Policy:* Removed language regarding obsolete Directive: ~~Following VHA Directive 2008-079, Research Participant Outreach Program,~~T ~~t~~he Durham VA Medical Center will establish, implement, and evaluate a Research Participant Outreach program by promoting the ~~and ensure local Investigators have an adequate supply of the brochure~~ "Volunteering in Research – Here are some things you need to know~~.~~" brochure, in addition to conducting Research Week activities and other community outreach activities. *Section 1.1.1, Study Team Personnel:* Removed requirement to provide research brochure: The Principal Investigator ~~is responsible for making available~~ may provide the informational brochure, "Volunteering in Research – Here are some things you need to know," to potential research participants in settings where they recruit potential research study participants, to ~~each~~ prospective participants and/or surrogates where necessary, or when ~~an~~ individuals are ~~is~~ approached to take part in a project. These brochures provide Veterans with a balanced view of VA research and summarize Veterans' rights and welfare if they decide to participate as subjects. ~~This requirement applies when written documentation of informed consent is waived, but not when informed consent has been waived. The Principal~~

SOP #	Title	Change Rationale
		~~Investigator is also responsible to ensure that all Research Study staff assigned to their individual study protocols are aware of and compliant with VHA Directive 2008-079 Research Participant Outreach Program, as well as the supporting VAMC Policy.~~ ***NOTE:*** *Copies of the brochure can be ordered in bulk from ~~the VA Office of Research and Development's Center on Advice and Compliance Help (COACH) at~~: ~~http://www.research.va.gov/programs/pride/resources/order.cfm~~.* http://www.research.va.gov/pubs/order_brochure.cfm *Section 3, Responsibilities:* Removed obsolete language: The ACOS for R&D is responsible for implementing the local Research Participant Outreach Program~~, ensuring initial education of Principal Investigators regarding VHA Directive 2008-079 Research Participant Outreach Program and the distribution of "Volunteering in Research" brochures,~~ and ensuring ~~local Investigators have~~ an adequate supply of the "Volunteering in Research" brochures.